

Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering Facepiece Respirator Fit: Part I

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Objectives

The objectives of this pilot study were to determine the test data variation to be expected for a future project to assess filtering facepiece respirator (FFR) (Figure 1) fit and facial dimension changes as a function of time and to investigate factors that affect those changes



Figure 1. Examples of FFRs.

Background

- Over three million American workers are required to wear respirators and receive annual fit tests in accordance with the 1998 Occupational Safety and Health Administration (OSHA) standard 29 CFR 1910.134
- Four commenters provided the basis for establishing the OSHA annual fit test standard:
 - Texas Chemical Council: found that virtually no individuals fail fit tests a year after initial test
 - Exxon Company: < 1% annual fit test failure rate
 - Lord Corporation: < 1-3% annual fit test failure rate
 - Hoffmann-La Roche: 7% switch to different sizes and/or models after 2 years
- Currently, there is no scientific study quantifying the benefit of annual fit testing
- Questions have been raised regarding the scientific validity of annual fit testing, and specifically the impact that weight loss or gain has on respirator fit
- In an effort to address these concerns, NIOSH initiated a first-of-its-kind study to assess respirator fit and facial dimension changes as a function of time for a sample of 220 subjects wearing FFR and to investigate factors that affect such changes
- This pilot was initiated to verify consistent data collection methods

Methods

- Ten subjects were trained to don and doff an FFR model using standardized videos
- The TSI PortaCount® instrument measured leakage into the FFR during five exercises
- Filter penetration for each FFR was measured so that face seal leakage (FSL) could be calculated
- The study included only subjects who:
 - passed the fit test and demonstrated, through a series of nine donnings, that they achieved adequate protection (a subject was considered to have achieved adequate protection when, after nine trial donnings, the 90th percentile total inward leakage (TIL) was 0.05 or less)
- Following the respirator fit tests, 13 traditional face measurements (Figure 2), height, weight, and a 3-D scan with the Cyberware Rapid 3D Digitizer (Figure 3) were collected
- The same data were collected at weeks two and four

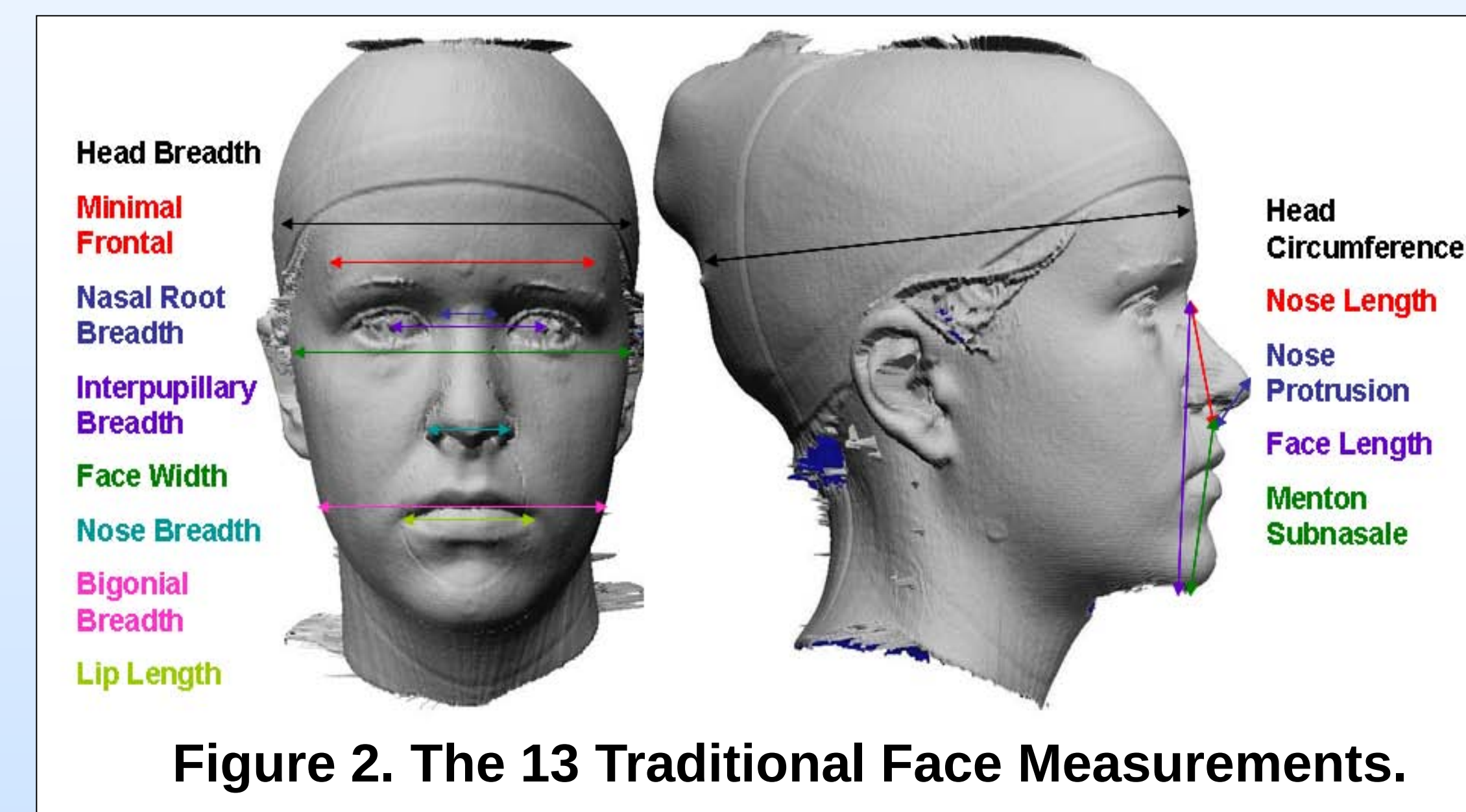


Figure 2. The 13 Traditional Face Measurements.

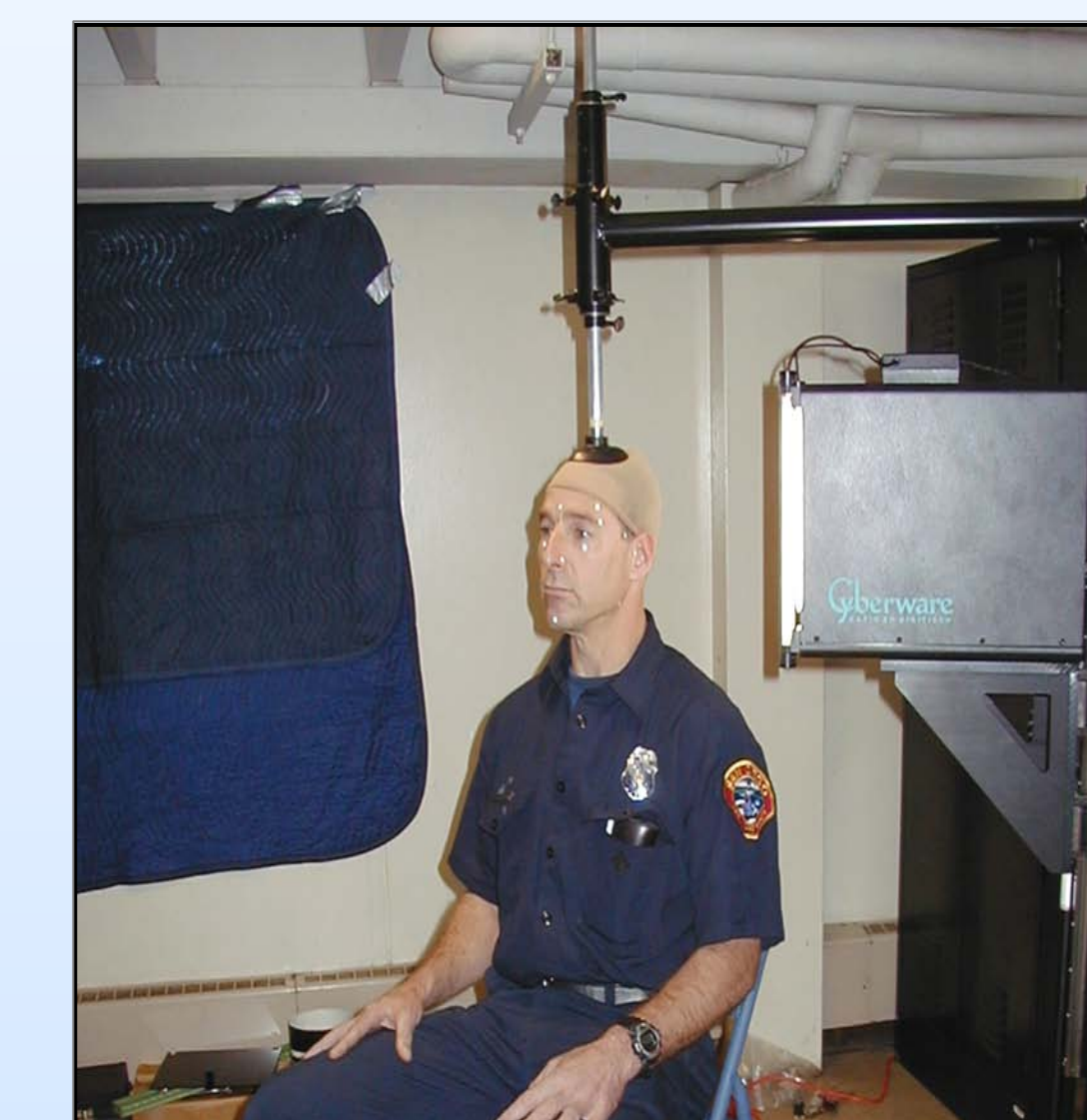


Figure 3. Individual being scanned with the Cyberware Rapid 3D Digitizer.

Results

- The mean face seal leakage of the 9 donnings for individual subjects ranged from 0.202% to 0.997% for the first test cycle, from 0.231% to 1.059% for the second test cycle, and from 0.248% to 2.234% for the third test cycle (Figure 4)
- The mean change in face seal leakage for the 10 subjects was 0.044% between cycles 1 and 2, and was 0.229% between cycles 1 and 3

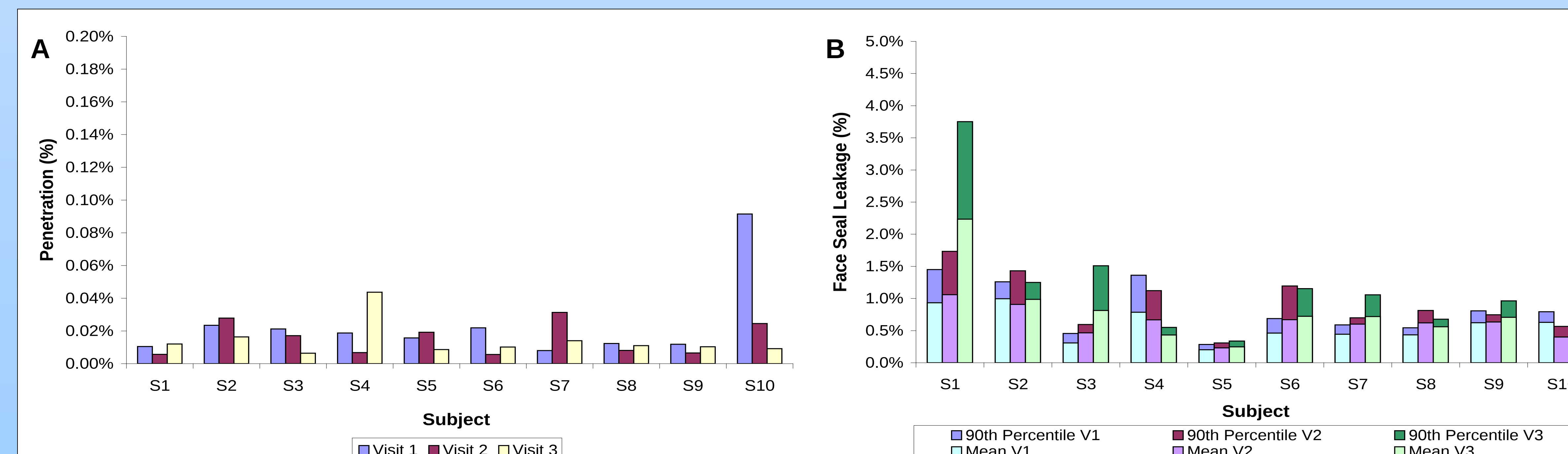


Figure 4. Graphs showing filter penetration (A) and face seal leakage (B) calculated by subtracting filter penetration from total inward leakage measurements for visits 1, 2 and 3 (V1, V2, and V3).

- Standard deviations for manual measurements were within the limits specified by the 1988 Anthropometric Survey of U.S. Army Personnel: Methods and Summary Statistics (Table 1)
- Facial variations between visits were within +/- 2 mm (Figure 5)

Table 1. Manual measurements for three subjects showing the mean, standard deviation and range of measurements for the 13 dimensions taken at baseline, 2 weeks and 4 weeks.

Dimension	Subject 1			Subject 2			Subject 3		
	mean	standard deviation	range	mean	standard deviation	range	mean	standard deviation	range
Bigonial Breadth	98	3	5	116	3	6	110	2	3
Face Width	132	2	4	137	1	1	140	3	5
Interpupillary Breadth	59	0	1	61	1	1	61	1	1
Lip Length	48	1	2	51	2	3	55	1	2
Face Length	120	2	4	112	1	2	133	1	2
Menton Subnasale	71	3	5	65	1	1	83	2	4
Nasal Root Breadth	15	0	0	17	1	1	19	1	1
Nose Breadth	36	1	2	31	0	0	35	0	0
Nose Protrusion	20	2	3	18	1	2	19	1	2
Nose Length	52	1	2	46	1	1	53	1	1
Minimal Frontal Breadth	99	1	2	103	2	3	104	1	2
Head Breadth	151	1	2	150	2	3	157	2	3
Head Circumference	560	3	5	556	6	11	585	5	10

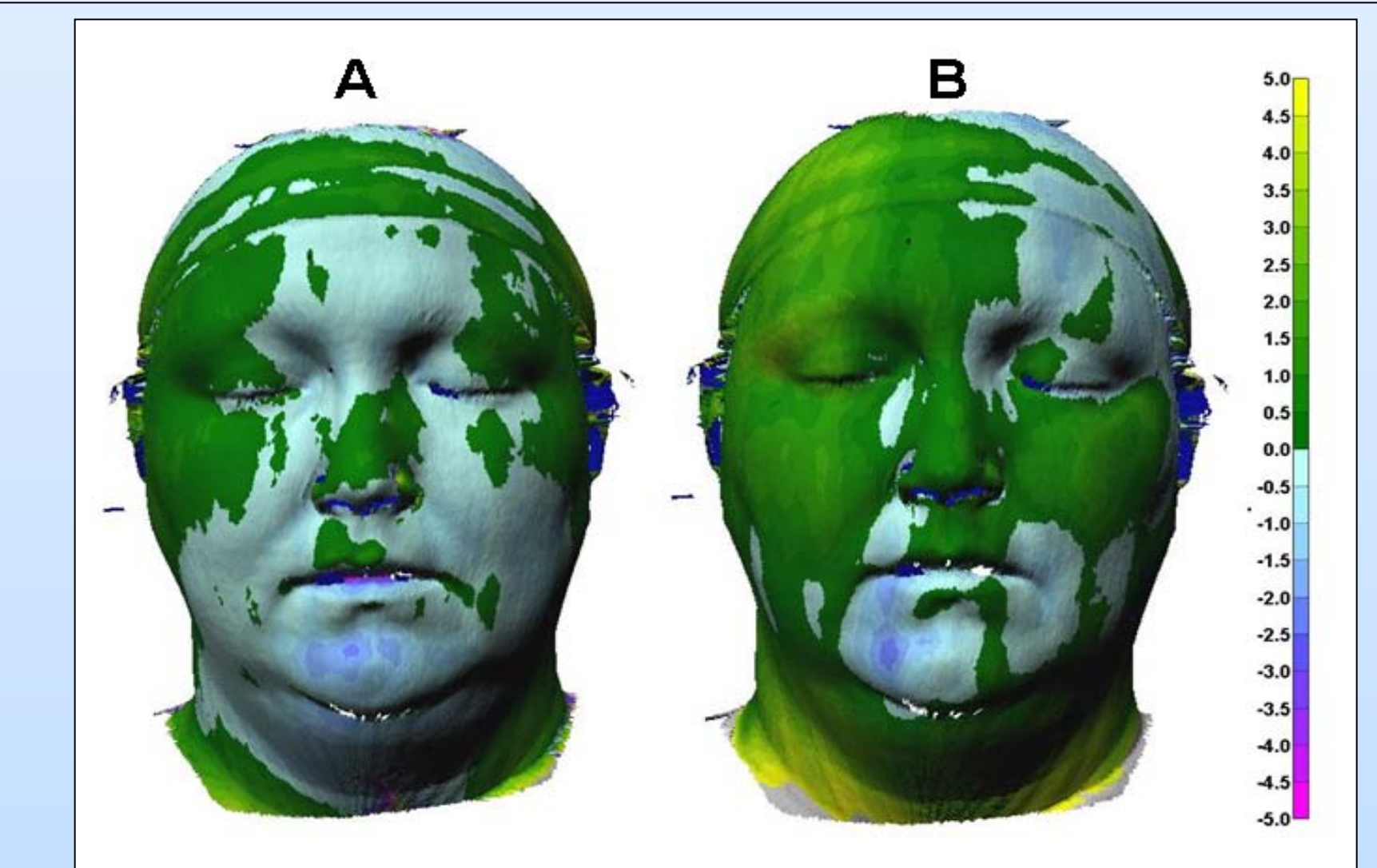


Figure 5. Scan data processed showing a baseline scan vs. a scan at week 2 (A), and baseline vs. week 4 (B) Variation was between +/-1mm, indicating no change.

Conclusions

- Although variability was observed between donnings and cycles, adequate fit was maintained for all 10 subjects
- Scan and manual data showed subject faces remained within measurement error over a period of four weeks

Future Directions

- Complete study with a representative sample of 220 subjects
- Conduct a pilot study using elastomeric respirators in conjunction with the overall study
- Assess 3-D data to determine ability to capture changes in facial characteristics over time

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